Supreme Court, U.S.
FILED
MAR 18 2003
OFFICE OF THE CLERK

No. 02-1007

IN THE

Supreme Court of the United States

DUKE UNIVERSITY,

Petitioner,

v.

JOHN M. J. MADEY,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

REPLY BRIEF

STEPHEN M. MCNABB
Counsel of Record
JOHN M. SIMPSON
JOHN A. BAUER
KAREN M. MORAN
CAROLINE M. MEW
FULBRIGHT & JAWORSKI L.L.P.
Counsel for Petitioner
801 Pennsylvania Avenue, N.W.
Washington, DC 20004
(202) 662-0200

179770

COUNSEL PRESS
(800) 274-3321 • (800) 359-6859

TABLE OF CONTENTS

Page

Table of Cited Authorities ii

Introduction 1

Argument 1

I. Dr. Madey Misrepresents Duke's Argument And The Basis Of The Federal Circuit's Decision 1

II. Madey's Proposed Experimental Use Standard Does Not Support The Denial Of Certiorari 4

III. Dr. Madey Cannot Dispute The Significance Of The Federal Circuit's Decision 6

Conclusion 8

TABLE OF CITED AUTHORITIES

Cases: *Page*

Embrex, Inc. v. Service Eng'g Corp., 216 F.3d 1343 (Fed. Cir. 2000) 2-3

Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 122 S. Ct. 1831 (2002) 3

Pitcairn v. United States, 547 F.2d 1106 (Ct. Cl. 1976) 4

Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858 (Fed. Cir. 1984) 3

Ruth v. Stearns-Roger Mfg. Co., 13 F. Supp. 697 (D. Colo. 1935) 2

Sawin v. Guild, 21 F. Cas. 554 (C.C.D. Mass. 1813) (No. 12,391) 2, 3, 6

Whittemore v. Cutter, 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600) 3, 6

Cited Authorities

Page

Other Authorities:

John P. Walsh *et al.*, *Working Through the Patent Problem*, 299 Science 1021 (Feb. 14, 2003) 7

10A Charles Alan Wright *et al.*, Federal Practice and Procedure: Civil § 2716 (3d ed. 1998) 3

The Compact Oxford English Dictionary 687 (2d ed. 1991) 6

Webster's Third New International Dictionary 1698 (1986) 6

INTRODUCTION

Beginning with the statement of the question presented, and continuing throughout the introduction, statement of facts, and argument, the brief in opposition gets this case backwards. Dr. Madey claims that Duke asked for a *per se* experimental use exemption for research universities and that the Federal Circuit limited the exemption to its historic scope. In fact, Duke sought an application of the experimental use exemption consistent with tradition and precedent, pursuant to which the exemption is available when academic scientific research is directed toward noncommercial objectives. The Federal Circuit, however, in a radical departure from past doctrine, announced a new *per se* rule denying the exemption to any and all academic scientific research because, the court explained, such research, even when purely noncommercial in nature, furthers the sponsoring university's "legitimate business [of] educating and enlightening students and faculty." App. at 25a. The question presented by this case is whether ***this*** *per se* rule, together with its peculiar rationale, should constitute the new law of the land. This question is of manifest importance and warrants immediate plenary review.

ARGUMENT

I. DR. MADEY MISREPRESENTS DUKE'S ARGUMENT AND THE BASIS OF THE FEDERAL CIRCUIT'S DECISION

According to Dr. Madey, "the Federal Circuit rejected Duke's efforts to transform the narrow experimental use defense into a *per se* general exemption allowing free use of patented inventions by nonprofit organizations" based on

"settled law defining the scope of the experimental use defense." Brief for Respondent in Opposition ("Resp. Br.") at 10. Dr. Madey is wrong about Duke's argument and the basis of the Federal Circuit's decision.

First, Duke is not arguing that nonprofit organizations are *per se* exempt from patent infringement and it is not advocating a "double standard." Resp. Br. at 20. Indeed, Dr. Madey has it backwards. Duke has argued throughout this litigation that research universities, like commercial enterprises, should be able to make noncommercial, experimental use of patents. In rejecting this argument, the Federal Circuit did not "stress[ ] that the district court had erred in not conducting a 'detailed analysis of the character, nature and effect of the uses.'" Resp. Br. at 14 (misquoting language that the Federal Circuit used in criticizing the decision in *Ruth v. Stearns-Roger Mfg. Co.*, 13 F. Supp. 697, 713 (D. Colo. 1935)). Instead, it adopted a *per se* rule that research universities are precluded from making noncommercial experimental use of patents "regardless of commercial implications" because such use furthers their "legitimate business objectives [of] educating and enlightening students and faculty." App. at 25a.

Second, the Federal Circuit did not decide this case on the basis of "settled law defining the scope of the experimental use defense." Resp. Br. at 10. From its inception, the experimental use exception to patent infringement has turned on whether the use was commercial in nature. *See Sawin v. Guild*, 21 F. Cas. 554, 555 (C.C.D. Mass. 1813) (No. 12,391) (patent infringement requires "an intent to use for profit"). That view prevailed for almost two centuries and, indeed, was embraced by the Federal Circuit in recent years. *See Embrex, Inc. v. Service Eng'g*

Corp., 216 F.3d 1343, 1349 (Fed. Cir. 2000) (experimental use exception does not protect research performed "expressly for commercial purposes"); *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984) (tests that have "definite, cognizable, and not insubstantial commercial purposes" not allowed under the experimental use exception). In this case, however, the Federal Circuit radically departed from this settled law, which Congress implicitly adopted in the 1952 Patent Act.

The Court's rationale for departing from the settled law turns the experimental use exception on its head. The experimental use exception always has permitted uses that were educational or enlightening. *See Whittemore v. Cutter*, 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600); *Sawin*, 21 F. Cas. 554. After the Federal Circuit's decision, however, entities that are dedicated to educating or enlightening – unlike avowedly commercial enterprises – are prohibited from making any experimental use of a patent. Thus, not only does the Federal Circuit's decision upset "the settled expectations of the inventing community," *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 122 S. Ct. 1831, 1841 (2002) (citation omitted), it does so for precisely the wrong reasons.

Consistent with the usual practice of appellate courts, the Federal Circuit did not enter summary judgment for Dr. Madey (the non-moving party) on the experimental use exception but instead remanded the case to the district court for further proceedings. *See* 10A Charles Alan Wright *et al.*, Federal Practice and Procedure: Civil § 2716, at 294 (3d ed. 1998). That remand, however, is an empty shell with respect to the experimental use exception. Contrary to Dr. Madey's suggestion, the Federal Circuit did not remand the case

"to develop a complete factual record of the character, nature, and effect of Duke's uses of the patented inventions." Resp. Br. at 15. It announced a new legal standard and directed the district court "to significantly narrow and limit its conception of the experimental use defense" accordingly. App. at 26a. The Federal Circuit, moreover, performed the dispositive analysis for the district court. According to the Federal Circuit, "Duke's acts appear to be in accordance with any reasonable interpretation of Duke's legitimate business objectives." *Id.* (footnote omitted). In particular, according to the Federal Circuit, the legitimate business of Duke includes "educating and enlightening students and faculty" and "increas[ing] the status of the institution and lur[ing] lucrative research grants, students and faculty." App. at 25a. And, according to the Federal Circuit, because the University's research projects "unmistakably further the institution's legitimate business objectives," it is prohibited from relying on the experimental use exception for research projects "regardless of commercial implications." *Id.* The Federal Circuit's decision forecloses Duke from relying on the experimental use exception on remand in this case and it effectively forecloses any other research university from relying on the exception in any other case involving the university's research projects.

II. MADEY'S PROPOSED EXPERIMENTAL USE STANDARD DOES NOT SUPPORT THE DENIAL OF CERTIORARI

Dr. Madey's own unease with the Federal Circuit's test is revealed by his unwillingness to defend it. Madey barely mentions the Court of Appeals' "legitimate business" test other than to argue that *Pitcairn v. United States*, 547 F.2d 1106 (Ct. Cl. 1976), was properly decided. Dr. Madey instead

proposes a different, extremely narrow experimental use exception that would be applicable to *both* non-profit research institutions and commercial enterprises. In Dr. Madey's view, the "experimental use" exception is limited to "verification and replication of the results of the inventor, as well as the invention itself and how it works for purposes of scientific understanding and advancement of knowledge." Resp. Br. at 18. Under Dr. Madey's standard, "[a] major manufacturing concern and a nonprofit university alike that limit exploration of a patented invention to 'ascertaining the sufficiency of the machine to produce its described effects,' will be entitled to rely on the experimental use defense." Resp. Br. at 17 (citations omitted).

In advocating a third test – one that falls between the commercial-noncommercial distinction of the historical test and the *per se* prohibition announced by the Court of Appeals – Dr. Madey confirms the importance of having the Supreme Court address the contours of the experimental use exception to patent infringement. Dr. Madey tries to suggest that the Federal Circuit embraced this standard by baldly proclaiming that "the Federal Circuit ordered a remand to determine whether Duke used the patented inventions regularly as they were intended to be used, not to verify their utility, but rather to obtain the benefits of the patented use." *Id.* Nothing in the Federal Circuit's opinion supports this assertion. Instead, the Federal Circuit concluded that Duke's status as a research university precluded it from relying on the experimental use exception altogether.

In any event, the case law has never recognized the distinction advocated by Dr. Madey. The experimental use exception always has applied *both* to uses "for the purpose of ascertaining the sufficiency of the machine to produce its

desired effects" (Dr. Madey's position) *and* uses for "philosophical experiments." *Whittemore v. Cutter*, 29 F. Cas. at 1121. Dr. Madey ignores the inconvenient "philosophical experiments" prong of this test. In early nineteenth century parlance, "philosophical" meant "[p]ertaining to, or used in the study of, natural philosophy, or some branch of physical science; physical, scientific." The Compact Oxford English Dictionary 687 (2d ed. 1991); *see also* Webster's Third New International Dictionary 1698 (1986) ("philosophical" meant "characterized by learning or the spirit of inquiry: scholarly" and "of or relating to the physical sciences"). The experimental use exception, therefore, always has been understood to apply to uses of a patent in scientific experiments, and the determinative factor always has been whether the uses were commercial in nature. *See Sawin*, 21 F. Cas. at 555. It has not, as Dr. Madey argues, applied only to uses of patented inventions to determine whether they work.

III. DR. MADEY CANNOT DISPUTE THE SIGNIFICANCE OF THE FEDERAL CIRCUIT'S DECISION

Contrary to Dr. Madey's suggestion, Duke does not "oppose[ ] the statutory monopoly given to inventors by Congress pursuant to the Constitution." Resp. Br. at 24. It agrees with Dr. Madey that, before this case, patent law struck an appropriate balance between protecting patent rights and permitting important noncommercial research to proceed. It disagrees with Dr. Madey, however, over whether the Federal Circuit's decision has upset that delicate balance with adverse consequences for scientific progress in this country. Dr. Madey's argument that research will not be impaired is based on the mistaken premise that the Federal Circuit's

decision did not change the law pertaining to the availability of the experimental use exception to noncommercial research by universities. Because Dr. Madey's premise is wrong, his conclusion is equally invalid.

Not only is Dr. Madey wrong about the law, he is wrong about the perception within the academic and scientific communities about what the law permitted. Patent law historically has not unduly inhibited academic research because parties universally have understood that it permitted researchers to conduct non-commercial experiments without the threat of possible infringement. The Federal Circuit's opinion has changed that understanding. Indeed, an authority cited by Dr. Madey concludes that "the effective elimination of the research exemption by the recent Circuit Court *Madey v. Duke University* decision may undermine the informal exemption that, as our interviews suggest, is important for open science." John P. Walsh *et al.*, *Working Through the Patent Problem*, 299 Science 1021, 1021 (Feb. 14, 2003) (footnote omitted). And, as the *amici* have confirmed, "[t]he Federal Circuit's opinion in this case will have a very damaging chilling effect on all university-based scientific research." Brief for Association of American Medical Colleges, *et al.*, as *Amici Curiae* in Support of Petitioner, at 13.

CONCLUSION

The Court should grant the petition for writ of certiorari to the United States Court of Appeals for the Federal Circuit.

Respectfully submitted,

STEPHEN M. MCNABB
Counsel of Record
JOHN M. SIMPSON
JOHN A. BAUER
KAREN M. MORAN
CAROLINE M. MEW
FULBRIGHT & JAWORSKI L.L.P.
Counsel for Petitioner
801 Pennsylvania Avenue, N.W.
Washington, DC 20004
(202) 662-0200